Prof Ainsley Newson's responses to questions about data

Dear Jurors

You have been asking some great questions on VisionsLive about data, so I gathered them together and asked Prof Ainsley Newson, who you will meet on Sunday 23rd March on Zoom, for her reflections on them.

Her first response was: "Wow, they are good questions!"

Prof Newson is currently running a project about what kind of governance system is needed to keep genomic data safe and ensure it's used responsibly (see: https://lineagestudy.org.au/). However that project is quite high level, so Prof Newson has provided some responses to your questions below. She did note that not all of these questions have good answers yet – some things are still uncertain.

Keep the good questions coming!

Stacy

Q: We have a concern about scope creep: how do we ensure the data collected by genomic NBS cannot be repurposed by a change in government policy

A: There is disagreement about whether data collected this way *should or should not* be repurposed. Creating a dataset from other population wide use of genomics is under consideration from government). The jury might want to consider whether or not they think that this kind of repurposing is OK.

Either way, and as for other kinds of health data at present, we would have to rely on good processes and good governance systems.

Q: Can genomic data be anonymised?

A: Genomic data, at least when it's a bigger amount of data from a single individual, cannot be fully anonymised. Several papers have shown this over the years. De-identification is probably the best we can do. For regulatory purposes, it then becomes about what the reasonable protections should be, and what people are comfortable with, risk-wise.

(De-identification means removing obvious identifiers – things like name, date of birth, address. Anonymisation means making changes to the data so that it's impossible to work out who you are, even if the genomic data is combined with other data sources.)

Q: Who would have access to the genomic data from NBS? For example, could it be accessed by insurance companies, policing, intelligence services, budget

planning, social security? Could the data be accessed via subpoena in court cases?

A: Insurance is pretty well safeguarded now (they don't have access to data, but they can currently ask about results – they may not be able to in the future). Policing and other agencies is more of a black box, and I'd say is a regulatory gap for all genomic information, including anything from NBS. Forensic scientists working with the police have obtained access to bloodspot cards to help in situations like identifying human remains after natural disaster events.

The question I'd suggest is most important is: what would be *new* here if we added genomic sequencing?

Q: Who owns the genome? Who owns the data from genomic tests?

A: I would say no one person or entity owns the genome (humanity owns it, or at least it's collectively owned).

As to who owns data, my own take is that it is unlikely to be the person who was tested. The question is rather who commissioned and who paid for the test.

Prof Newson directed Stacy to a recent paper by law academic Prof Jane Nielsen, which Stacy has summarised below:

- Australian law does not allow genomic data to be recognised as property that can be owned, so the law does not allow us to own the data derived from our own samples
- Even if we could own the data from our own genome as individuals, that would not give us total control over its use.
- However, we still have rights in relation to our own genomic data: we have a right to consent or not to the collection of our data for specified uses, and we also have a right to privacy.
- This means consent and good communication are critically important.

https://onlinelibrary.wiley.com/doi/epdf/10.1111/imj.16573

Q: Where would the data be stored? Could data storage in some States be less secure than in others?

A: Data likely to go on a secure cloud based server. Each state has its own laws, and data security standards for this data could be specified. Ongoing projects like the 'National Approach to Genomic Information Management (NAGIM)' and the governance framework that Prof Newson's LINEAGE project will develop will help here. Of course the goal would be, in line with current federal policy about NBS, that every newborn in Australia would have the same experience and be subject to the same standards

Q: How would genomic information be accessed by parents, and doctors (e.g. would it be accessible to GPs? would access be via some kind of online platform? Could this information be incorporated into MyHealthRecord? Could the child have access to the data later in life?

A: This is all to be decided. Medicare currently cuts off to parents when a child is 14 and then the child can decide whether their parents can see their records. The same could potentially happen here. I think a reasonable goal, if data is to be kept (which is not a foregone conclusion) would be that it could be interrogated over time, especially by health professionals. If individuals would have access to their sequence data I'd ask jurors to reflect on whether this would be meaningful and what other consequences might arise as a result